



Temporary Tattoos: Raising Consumer Awareness of Safety

Food & Drug Administration
Center for Food Safety and Applied Nutrition
Office of Cosmetics and Colors

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Overview

- Definitions
- Consumer uses
- Types of temporary tattoos
 - Transfers and decals
 - Henna tattoos
 - Black henna tattoos with p-phenylenediamine (PPD)
 - Other types of temporary tattoos
- Potential risks
- FDA oversight
- Adverse reactions
- Reporting

Temporary tattoo definitions

- Non-permanent decorations of the skin
 - Plant-based dyes and other stains that bind to keratin in skin (last days to weeks)
 - Drawn, painted, or air-brushed directly on the skin
 - Applied using decals or transfers with a backing
- Not injected with needles
 - Injected inks are tattoos or permanent make-up

FDA authority over cosmetics

- FDA can take action against harmful cosmetics on the market
- FDA does not have the authority to approve cosmetics before they go on the market
- The manufacturer is responsible for making sure cosmetics are safe; may do testing or use available data for similar products
- FDA does not have the authority to require firms to report their test data and does not set standards for that testing
- Color additives used in cosmetics must be pre-approved by FDA
 - 21 CFR Parts 70, 71, 73, 74, 80, 81, and 82
 - Other applicable regulations

Temporary tattoo consumer uses

- Form of self-expression and body decoration
- Cultural and ceremonial associations
 - Designs and duration of staining have meaning
 - The darker the stain, the more luck for the wearer
 - The longer the stain lasts, the better the marriage will be
- Advantages over permanent tattoos
 - Consumers perceive that this is a safer alternative
 - Does not involve needles
 - Some decals or transfers may contain color additives that are approved for application to the skin
 - Designs fade and can easily be re-applied or changed to suit the situation

Types of temporary tattoos

- Types of temporary tattoos
 - Transfers and decals
 - Henna tattoos
 - Black henna tattoos with p-phenylenediamine (PPD)
 - Jagua
 - Ballpoint pen decorations

Transfers and decals



- Regulated as cosmetics
- Direct application to the skin
 - Must use color additives that are approved for use in cosmetics
- Exception – functional impermeable barrier (plastic backing)
 - Prevents direct contact with the skin
 - FDA does not insist that the color additives used be limited to those approved for use in cosmetics
 - Manufacturers have responsibility to obtain appropriate test data
 - Must establish that there is a functional barrier to migration of any color additives not approved for use in cosmetics

Henna tattoos

- Dried leaf of lawsonia plant
- Imparts a brown, orange-brown, or reddish-brown tint
- Mixed with other substances that alter shade and duration of staining
 - lemon
 - eucalyptus oil
- Powder, paste, or liquid form
- Permitted for hair coloring
- Not permitted by FDA for use on the skin



Black henna

- Contains or consists of hair dye ingredient
 - p-Phenylenediamine (PPD)
 - Mixed with henna and other ingredients
- Added to give darker stain and last longer
- PPD is a known skin sensitizer or allergen
- Not permitted for use on skin



Jagua & newer temporary tattoos

- Jagua tattoos
 - From unripened fruit of S. American tree
 - Used by indigenous Amazonian tribes to stain skin
 - Deep blue-black color formed
- Ballpoint pen decorations
- Safety not established for either of these

Where to find temporary tattoos?

- Vending machines, bubble gum inserts
- Resorts, beaches, holiday locations
- Ethnic marketplaces, beauty parlors, kiosks in shopping malls
- Festivals, street fairs, amusement parks
- Cultural celebrations
 - Weddings (Mehndi)
 - Birthday parties

Who applies temporary tattoos?

- Vendors who are not necessarily trained or certified
 - Little or no oversight from local or state authorities
 - FDA does not have authority over practices of vendors
- Vendors who may not know of adverse reactions
 - Reactions may occur 1-3 days after application
- Vendors who may not know that harmful ingredients are present in the product
 - Ingredient lists not required in labeling of professional use products

Import Alert 53-14

- Intensified coverage of temporary tattoos
 - Using non-certified color additives
 - Non-permitted color additives
 - Failure to bear ingredient declaration
 - Labelled “FDA-approved”
- Initiated in response to trade complaints from manufacturers and distributors

Import Alert 53-19

- Prevents entry of henna-based skin color into the U.S.
- Labels declare henna as an ingredient
- Labels depict designs on the hands and feet

Compare and contrast

Properties

Henna

- For staining: apply for 2-12 hours
- Lawsone binds to keratin after mixing with acid and oils
- Color deepens over 2-4 days
- Red to red-brown stain, no black
- Usually lasts days, up to 2-6 weeks depending upon exposure to sun, water, scrubbing

PPD

- For staining: apply for <1 hour to 2-6 hours
- Dyes the skin whether mixed with henna or alone
- Color is immediate
- Brown or black to blue-black stain
- Lasts 2-6 weeks depending upon exposure to sun, water, scrubbing

Compare and contrast

FDA oversight

Henna

- Approved only for use as a hair dye
- Not a coal-tar hair dye so does not require a warning statement and directions for a patch test
- Not approved for use on the skin

PPD

- Exempted from approval under FD&C Act when used as a hair dye
- Requires a warning statement and directions for a patch test
- Not approved for use on the skin

Allergic reactions



Compare and contrast

Acute effects of injury may include:

Henna

- Low allergenic potential
 - Sneezing, conjunctivitis, swelling face, airway constriction, urticaria (hives)
- Can trigger a hemolytic event in children with an inherited form of red blood cell enzyme deficiency (glucose-6-dehydrogenase deficiency)
 - commonly, but not accurately, called favism

PPD

- Rash emerges 3 to 5 days
- Becomes oozing open sores that can last several weeks
- Results in scarring, changes in skin pigmentation
- May have increased UV sensitivity, requiring sunscreen protection

Compare and contrast

Long-term effects of injury may include:

Henna

- Highest risk: User may become sensitized or allergic to essential oils and other chemicals mixed with henna to make the stain darker and last longer

PPD

- Scarring, increased sensitivity to sunlight
- Life-long allergy to hair dye
- Cross-reactive allergies to related chemicals, such as
 - textile or synthetic dyes
 - sulfonamide antimicrobials
 - some sunscreens
 - local anesthetics
 - rubber and latex

Reporting reactions to temporary tattoos

- First, if you are having a reaction to a cosmetic, contact your healthcare provider for treatment.
- If you've had a reaction to a temporary tattoo or any cosmetic product, FDA wants to know.
 - The law doesn't require cosmetic companies to report problems to FDA.
 - Information reported is important to help FDA monitor the safety of cosmetics on the market.
- Consumers, health care providers, and salon professionals can report problems.
 - It is helpful if only one person files a report on each incident.

Where to report a problem

- Contact MedWatch, FDA's problem-reporting program
 - 1-800-332-1088
 - MedWatch voluntary report online at
<http://www.fda.gov/safety/medwatch/default.htm>
- Contact the consumer complaint coordinator in your area
 - <http://www.fda.gov/safety/reportaproblem/consumercomplaintcoordinators/default.htm>

How to report a problem

- Include the following information in your report
 - Name and contact information for the person who had the reaction
 - Age, gender, and ethnicity of the person who used the product
 - Precise name of the product and the manufacturer
 - A description of the reaction and treatment, if any
 - Healthcare provider's name and contact information, if medical attention was provided
 - When and where you bought the product

Conclusions

- Black henna, hair dyes or PPD that is painted on the skin:
 - May leave scars or cause skin to be sensitive to UV light
 - Allergies: May cause permanent life-long allergies
 - hair dye
 - cross-reactive to dyed clothing or to rubberized products
- Approach temporary tattoos with caution:
 - You and the artist may not know that PPD is in a product that is applied to your skin
 - Not all temporary tattoos are known to be safe, and some can be harmful.
- Report any adverse reactions

For more information on temporary tattoos

<http://www.fda.gov/Cosmetics/ProductsIngredients/Products/ucm108569.htm>

Thank you!

For your time and interest.

We'll be back in just a few minutes to respond to questions you've submitted.